Attorney's Docket No.: 14555-003004 / :270/058

OFFICIAL COMMUNICATION

FACSIMILE

FOR THE PERSONAL ATTENTION OF:

EXAMINER L. WELLS

GROUP 1617 FAX NO: (703) 746-5231

Number of pages including this page 30

Applicant : Gary S. Hahn et al.
Serial No. : 09/992,491
Filed : November 21, 2001

Art Unit : 1617
Examiner : L. Wells

FACSIMILE COMMUNICATION

Title : Topical Product Formulations Containing Strontium for Reducing Skin Irritation

Commissioner for Patents
Washington, D.C. 20231

Sir:

Attached to this facsimile communication cover sheet is a Response to Request for Information, faxed this 24th day of April, 2003, to Group 1617, the United States Patent and Trademark Office.

Respectfully submitted,

Date: April 24, 2003

Diane L. Gardner
Reg. No. 36,518

PTO Customer No. 20985
Fish & Richardson P.C.
4350 La Jolla Village Drive, Suite 500
San Diego, California 92122
Telephone: (858) 678-5070
Fax: (858) 678-5099

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Attorney's Docket No.: 14555-003004 / 270/058

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant : Gary S. Hahn et al. Art Unit : 1617
Serial No. : 09/992,491 Examiner : L. Wells
Filed : November 21, 2001
Title : TOPICAL PRODUCT FORMULATIONS CONTAINING STRONTIUM FOR REDUCING SKIN IRRITATION

Commissioner for Patents
Washington, D.C. 20231

RESPONSE TO REQUEST FOR INFORMATION

In a telephone conversation on April 22, 2003, the Examiner requested additional information with respect to claims in six applications. The applications are listed as follows:

U.S. Serial No. 10/189344
U.S. Serial No. 10/033194
U.S. Serial No. 10/003478
U.S. Serial No. 10/001935
U.S. Serial No. 09/853828
U.S. Serial No. 09/833221

The Examiner requested copies of the claims from each of the applications listed above in which the claims are drawn to strontium, as opposed to another metal.

In a follow up conversation on April 24, 2003, the Examiner confirmed that only copies of claims that are currently pending need be supplied. The single application that remains pending as of even date is U.S. Serial No. 10/189344.

CERTIFICATE OF TRANSMISSION BY FACSIMILE

I hereby certify that this correspondence is being transmitted by facsimile to the Patent and Trademark Office on the date indicated below.

April 24, 2003
Date of Transmission

Signature

Norman Green
Typed or Printed Name of Person Signing Certificate

Applicant : Gary S. Hahn et al.
Serial No. : 09/992,491
Filed : November 21, 2001
Page : 2 of 2

Attorney's Docket No.: 14555-003004 / 270/058

A Preliminary Amendment as well as a Supplemental Preliminary Amendment have been filed in this application. The pending claims are attached.

Please apply any charges or credits to Deposit Account No. 06-1050.

Respectfully submitted,

Date: April 24, 2003

Diane L. Gardner
Reg. No. 36,518

PTO Customer No. 20985
Fish & Richardson P.C.
4350 La Jolla Village Drive, Suite 500
San Diego, California 92122
Telephone: (858) 678-5070
Facsimile: (858) 678-5099

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Attachment

What is claimed is:

CANCELLED 1. A composition for topical application to an animal subject comprising

a topical vehicle;

an irritant ingredient contained in an amount capable of inducing skin irritation in said subject; and

an anti-irritant amount of aqueous-soluble divalent strontium cation.

CANCELLED 2. The composition of claim 1 comprising strontium cation in a concentration of from about 10 mM to about 3000 mM.

A. 2 CANCELLED 3. The composition of claim 1 comprising strontium cation in a concentration of from about 50 mM to about 2000 mM.

CANCELLED 4. The composition of claim 1 comprising strontium cation in a concentration of from about 100 mM to about 1000 mM.

CANCELLED 5. The composition of claim 1 comprising strontium cation in a concentration of from about 250 mM to about 500 mM.

CANCELLED 6. The composition of claim 1 comprising an amount of strontium cation capable of inhibiting mean cumulative skin irritation attributable to said irritant ingredient in a susceptible human population by at least about 20%

CANCELLED 7. The composition of claim 6 wherein said inhibition of skin irritation represents an average reduction in one or more of sting, burn and itch in a susceptible human population upon topical application of said composition, as compared to the level of irritation induced in said population upon topical application of a control formulation containing said irritant ingredient in a vehicle without said strontium cation.

CANCELLED 8. The composition of claim 1 comprising an amount of strontium cation capable of inhibiting by at least about 40% the cumulative skin irritation attributable to said irritant ingredient in at least 10% of the susceptible human population.

CANCELLED 9. The composition of claim 8 wherein said inhibition of skin irritation represents an average reduction in one or more of sting, burn and itch in at least 10% of the susceptible human population upon topical application of said composition, as compared to the level of irritation induced in said at least 10% of the population upon topical application of a control formulation containing said irritant ingredient in a vehicle without said strontium cation.

CANCELLED 10. The composition of claim 1 wherein said composition is a cosmetic product.

CANCELLED 11. The composition of claim 10 wherein said composition comprises a skin exfolient, skin peel or skin cell renewal agent.

CANCELLED 12. The composition of claim 10 wherein said irritant ingredient is selected from the group consisting of carboxylic acids, keto acids, α-hydroxy acids, β-hydroxy acids, retinoids, peroxides, and organic alcohols.

CANCELLED 13. The composition of claim 12 wherein said irritant ingredient comprises lactic acid or a salt thereof.

CANCELLED 14. The composition of claim 12 wherein said irritant ingredient comprises glycolic acid or a salt thereof.

CANCELLED 15. The composition of claim 12 wherein said irritant ingredient comprises salicylic acid or a salt thereof.

CANCELLED 16. The composition of claim 12 wherein said irritant ingredient comprises a combination of lactic acid and salicylic acid, or salts thereof.

CANCELLED 17. The composition of claim 12 wherein said irritant ingredient comprises capryloyl salicylic acid or a salt thereof.

CANCELLED 18. The composition of claim 12 wherein said irritant ingredient comprises citric acid or a salt thereof.

CANCELLED 19. The composition of claim 12 wherein said irritant ingredient is a retinoid selected from tretinoin, retinol, retinal and derivatives thereof.

CANCELLED 20. The composition of claim 12 wherein said irritant ingredient comprises benzoyl peroxide.

CANCELLED 21. The composition of claim 12 wherein said irritant ingredient comprises acetic acid or a salt thereof.

CANCELLED

22. The composition of claim 12 wherein said irritant ingredient comprises one or more of the group consisting of l-pyrrolidone-5-carboxylic acid, capryloyl salicyclic acid, α-hydroxy decanoic acid, α-hydroxy octanoic acid, gluconolactone, methoxypropyl gluconamide, oxalic acid, malic acid, tartaric acid, mandelic acid, benzylic acid, gluconic acid, pyruvic acid and phenol.

CANCELLED

23. The composition of claim 12 wherein said irritant ingredient comprises trichloroacetic acid of a salt thereof.

CANCELLED

24. The composition of claim 12 wherein the pH of the composition is in the range of 1 to 6.

CANCELLED 25. The composition of claim 12 wherein the pH of the composition is in the range of 3 to 5.

CANCELLED 26. The composition of claim 12 having a concentration of said irritant ingredient of from about 0.1% to about 50%

CANCELLED 27. The composition of claim 12 having a concentration of said irritant ingredient of from about 0.5% to about 20%

CANCELLED 28. The composition of claim 1 wherein said composition is an antiperspirant or deodorant product.

CANCELLED 29. The composition of claim 1 wherein said composition is a sunscreen, tanning or sunburn treatment product.

CANCELLED 30. The composition of claim 1 wherein said composition is an insect repellant product.

CANCELLED 31. The composition of claim 10 wherein said composition is a shaving or hair removal product selected from the group consisting of depilatory, bracer, cream, foam, gel and aftershave products.

CANCELLED 32. The composition of claim 10 wherein said composition is a hair care or hair treatment product.

CANCELLED 33. The composition of claim 32 wherein said composition is selected from the group consisting of shampoo, conditioner, colorant, dye, bleach, permanent wave and hair straightener products.

CANCELLED 34. The composition of claim 10 wherein said composition is selected from the group consisting of cleansers, astringents, toners, rinses, serums and masks.

CANCELLED 35. The composition of claim 10 wherein said composition is a facial cosmetic product.

36. The composition of claim 10 wherein said composition is selected from the group CANCELLED consisting of creams, lotions and moisturizers.

CANCELLED

37. The composition of claim 1 wherein said composition is selected from the group consisting of soaps and detergents.

CANCELLED

38. The composition of claim 1 wherein said composition is a topical drug product.

CANCELLED 39. The composition of claim 38 wherein said irritant ingredient is capsaicin.

CANCELLED

40. The composition of claim 38 wherein said composition is selected from the group consisting of antibiotic, analgesic, contraceptive, anti-acne and anti-dandruff products.

CANCELLED

41. The composition of claim 40 wherein said irritant ingredient is benzoyl peroxide.

CANCELLED

42. The composition of claim 1 wherein said composition is formulated as a rectal or vaginal suppository, foam, cream, gel or ointment.

CANCELLED

43. The composition of claim 1 wherein said composition is formulated for administration to the mouth, throat or lip.

CANCELLED 44. The composition of claim 43 formulated as a lozenge, mouthwash or gargle.

CANCELLED

45. The composition of claim 1 formulated as a liquid, gel, cream, emulsion, suspension or stick.

CANCELLED

46. The composition of claim 1 formulated with a physical applicator.

CANCELLED

47. The composition of claim 46 wherein said physical applicator is selected from the group consisting of cloths, tissues, swabs, bandages and wet wipes.

CANCELLED

48. The composition of claim 1 further comprising, as counteranions to said strontium cation, one or more topically acceptable anion species.

CANCELLED

49. The composition of claim 48 further comprising, as counteranions to said strontium cation, one or more anion species selected from the group consisting of nitrate, sulfate, halogen, carbonate, bicarbonate, hydroxide, oxide, peroxide, nitrite, sulfide, bisulfate, persulfate, glycerophosphate, hypophosphate, borate and titanate inorganic anions, and carboxylic acid, alkoxylate, amino acid, peptide, saturated and unsaturated organic acid, and saturated and unsaturated fatty acid organic anions.

CANCELLED

50. The composition of claim 48 wherein said one or more of said counteranions is an organic anion selected from the group consisting of citrate, oxalate, acetate, gluconate, lactate, tartrate, maleate, benzoate, propionate, salicylate, ascorbate, formate, succinate, folinate, aspartate, phthalate, oleate, palmitate, stearate, lauryl sulfate, lanolate, myristate, behenate, caseinate, cyclamate, pantothenate, polyaminopolycarboxylates, saccharin, thioglycolate, laurate, methylparaben, propylparaben, ricinoleate and sorbate organic anions.

CANCELLED 51. The composition of claim 48 wherein said anion species includes nitrate.

CANCELLED 52. The composition of claim 48 wherein said anion species includes sulfate.

CANCELLED 53. The composition of claim 48 wherein said anion species includes a halogen selected from chloride and fluoride anions.

CANCELLED 54. The composition of claim 1 further comprising at least one second anti-irritant agent.

CANCELLED 55. The composition of claim 54 wherein the total amount of said strontium cation and said second agent is capable of inhibiting mean cumulative skin irritation attributable to said irritant ingredient in a susceptible human population by at least about 20%

CANCELLED 56. The composition of claim 54 wherein the total amount of said strontium cation and said second agent is capable of inhibiting by at least about 40% the cumulative skin irritation attributable to said irritant ingredient in at least 10% of the susceptible human population.

CANCELLED 57. The composition of claim 54 wherein said second agent is selected from the group consisting of potassium channel mediating, regulating or blocking agents, calcium channel blocking or regulatory agents, sodium channel blocking agents, steroids, non-steroidal anti-inflammatory agents, aloe vera, chamomile, α-bisabolol, cola nitada extract, green tea extract, tea tree oil, licorice extract, allantoin, urea, caffeine and other xanthenes, and glycyrrhizic acid and its derivatives.

CANCELLED 58. An composition for inhibiting skin irritation in an animal subject comprising an anti-irritant amount of aqueous-soluble divalent strontium cation and a topical vehicle.

CANCELLED 59. The composition of claim 58 comprising strontium cation in a concentration of from about 10 mM to about 3000 mM.

A-2

CANCELLED 60. The composition of claim 58 comprising strontium cation in a concentration of from about 50 mM to about 2000 mM.

CANCELLED 61. The composition of claim 58 comprising strontium cation in a concentration of from about 100 mM to about 1000 mM.

AMENDED 62. The composition of claim 58 comprising strontium cation in a concentration of from about 250 mM to about 500 mM.

A-3

CANCELLED 63. The composition of claim 58 wherein said inhibition of skin irritation represents a reduction in skin irritation attributable to a pre-existing human skin disease or skin irritation condition.

A-4

AMENDED A-5 64. The composition of claim 63 wherein said skin irritation is attributable to atopic or allergic contact dermatitis, eczema, psoriasis or infectious disease.

65. The composition of claim 63 wherein said skin irritation is attributable to environmental exposure to one or more of sunlight, low humidity, wind, cold temperature, or hot and humid conditions.

AMENDED A-6

AMENDED A-7

66. The composition of claim 63 wherein said skin irritation is attributable to exposure to an irritating chemical agent.

67. The composition of claim 66 wherein said irritating chemical agent exposure is attributable to application of a topical product.

68. The composition of claim 67 wherein said product is selected from the group consisting of antiperspirant, deodorant, sunscreen, tanning, sunburn treatment, insect repellant, exfolient, skin peel, skin cell renewal, fragrance, shaving or hair removal, hair care or hair treatment, cleanser, astringent, toner, rinse, serum, masks, facial cosmetic, cream, lotion, moisturizer, soap, detergent, and topical drug products.

69. The composition of claim 67 wherein said composition is packaged with instructions directing administration of said composition before, with or following administration of said topical product.

70. The composition of claim 66 wherein said irritating chemical agent exposure is attributable to insect sting or bite, or to plant exposure.

71. The composition of claim 63 wherein said skin irritation is attributable to one or more of shaving, skin cleansing or bathing, sweating, and physical skin trauma.

72. The composition of claim 58 wherein said skin irritation is attributable to dry skin.

73. The composition of claim 58 comprising an amount of strontium cation capable of inhibiting said skin irritation in subjects experiencing the same by an average of at least about 20%

74. The composition of claim 58 comprising an amount of strontium cation capable of inhibiting said skin irritation by at least about 40% in at least 10% of the subjects experiencing the same.

75. The composition of claim 58 wherein said composition is formulated as a rectal or vaginal suppository, cream, foam, gel, ointment, douche or enema.

76. The composition of claim 58 wherein said composition is formulated for administration to the mouth, throat or lip.

77. The composition of claim 76 formulated as a lozenge, mouthwash or gargle.

78. The composition of claim 58 formulated as a liquid, gel, cream, emulsion, suspension or stick.

79. The composition of claim 58 formulated with a physical applicator.

80. The composition of claim 58 further comprising, as counteranions to said strontium cation, one or more topically acceptable anion species.

81. The composition of claim 80 further comprising, as counteranions to said strontium cation, one or more anion species selected from the group consisting of nitrate, sulfate, halogen, carbonate, bicarbonate, hydroxide, oxide, peroxide, nitrite, sulfide, bisulfate, persulfate, glycerophosphate, hypophosphate, borate and titanate inorganic anions, and carboxylic acid, alkoxylate, amino acid, peptide, saturated and unsaturated organic acid, and saturated and unsaturated fatty acid organic anions.

82. The composition of claim 80 wherein said one or more of said counteranions is an organic anion selected from the group consisting of citrate, oxalate, acetate, gluconate, lactate, tartrate, maleate, benzoate, propionate, salicylate, ascorbate, formate, succinate, folinate, aspartate, phthalate, oleate, palmitate, stearate, lauryl sulfate, lanolate, myristate, behenate, caseinate, cyclamate, pantothenate, polyaminopolycarboxylates, saccharin, thioglycolate, laurate, methylparaben, propylparaben, ricinoleate and sorbate organic anions.

83. The composition of claim 58 further comprising at least one second anti-irritant agent.

AMENDED A.Y

84. The composition of claim 83 wherein said second agent is selected from the group consisting of potassium channel mediating, regulating or blocking agents, calcium channel blocking or regulatory agents, sodium channel blocking agents, steroids, non-steroidal anti-inflammatory agents, aloe vera, chamomile, α-bisabolol, cola nitada extract, green tea extract, tea

tree oil, licorice extract, allantoin, urea, caffeine and other xanthenes, and glycyrrhizic acid and its derivatives.

AMENDED 85. A method for inhibiting skin irritation associated with an irritant ingredient contained in an applied topical formulation, comprising topically administering to an human subject the composition of claim 1.

86. A method for inhibiting skin irritation in a human subject comprising topically administering to the subject the composition of claim 58.

87. The method of claim 86 wherein said composition is administered within about three hours prior to application to the subject of a second topical formulation containing an irritant ingredient.

88. The method of claim 86 wherein said composition is administered substantially simultaneously with application to the subject of a second topical formulation containing an irritant ingredient.

89. The method of claim 86 wherein said composition is administered to inhibit skin irritation attributable to a pre-existing human skin disease or skin irritation condition.

90. The method of claim 89 wherein said skin irritation is attributable to environmental exposure to one or more of sunlight, low humidity, wind, cold temperature, or hot and humid conditions.

91. The method of claim 89 wherein said skin irritation is attributable to exposure to an irritating chemical agent.

92. The method of claim 89 wherein said skin irritation is attributable to one or more of shaving, skin cleansing or bathing, and physical skin trauma.

Patent
274/152

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the Application of:

HAHN, Gary S. and THUESON, David O.

Serial No.: To be assigned

Filed: July 3, 2002

For: FORMULATIONS AND METHODS FOR REDUCING SKIN IRRITATION

Group Art Unit: To be assigned

Examiner: To be assigned

PRELIMINARY AMENDMENT

Box **Amendment**
Commissioner for Patents
Washington, D.C. 20231

Sir:

Transmitted herewith is an Amendment for the above-identified application.

IN THE SPECIFICATION:

At page 1, immediately following the title of the invention, please insert the following new paragraph:

--This application is a continuation of Serial No. 10/033,194, filed October 24, 2001, which is a continuation of Serial No. 09/853,282, filed May 10, 2001, which is a continuation of Serial No. 09/685,992, filed October 10, 2000, which is a continuation of Serial No. 08/860,993, filed June 23, 1997, and issued as U.S. Patent No. 6,139,850, which is a continuation-in-part of Serial No. 08/362,100, filed December 21, 1994 and issued as U.S. Patent No. 5,716,625. Parent

CERTIFICATE OF MAILING
(37 C.F.R. §1.10)

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Reynaldo Gallardo
Name of Person Mailing Paper

Signature of Person Mailing Paper

application Serial No. 08/860,993 was filed nationally on June 23, 1997 pursuant to 35 U.S.C. § 371, based on International Application No. PCT/US95/16985 (filed December 21, 1995). The present application and the aforesaid PCT application claim the benefit of the filing date of Serial No. 08/362,100 (December 21, 1994), as well as the benefit of all intervening applications, pursuant to 35 U.S.C. §§ 120 and 365.--

IN THE CLAIMS:

Please amend the claims as follows:

Please **cancel** claims 1-61 without prejudice or disclaimer.

62. (Amended) A composition for inhibiting skin irritation in an animal subject comprising an anti-irritant amount of at least about 50 mM of aqueous-soluble divalent strontium cation and a topical vehicle, wherein said composition is packaged with instructions directing the administration of said composition to the skin of an animal subject, and wherein said composition is effective to prevent or reduce skin irritation at the skin site where the composition is administered.

Please **cancel** claim 63 without prejudice or disclaimer.

64. (Amended) The composition of claim 62 comprising aqueous-soluble strontium cation in a concentration of from about 50 mM to about 2000 mM.

65. (Amended) The composition of claim 62 comprising aqueous-soluble strontium cation in a concentration of from about 100 mM to about 1000 mM.

66. (Amended) The composition of claim 62 comprising aqueous-soluble strontium cation in a concentration of from about 250 mM to about 500 mM.

84. (Amended) The composition of claim 62 comprising an amount of aqueous-soluble strontium cation capable of inhibiting said skin irritation in subjects experiencing the same by an average of at least about 20%.

85. (Amended) The composition of claim 62 comprising an amount of aqueous-soluble strontium cation capable of inhibiting said skin irritation by at least about 40% in at least 10% of the subjects experiencing the same.

95. (Amended) The composition of claim 62 further comprising, as counteranions to said aqueous-soluble strontium cation, one or more topically acceptable anion species.

96. (Amended) The composition of claim 95 further comprising, as counteranions to said aqueous-soluble strontium cation, one or more anion species selected from the group consisting of nitrate, [sulfate,] halogen, carbonate, bicarbonate, hydroxide, oxide, peroxide, nitrite, sulfide, bisulfate, persulfate, glycerophosphate, hypophosphate, borate and titanate inorganic anions, and carboxylic acid, alkoxylate, amino acid, peptide, saturated and unsaturated organic acid, and saturated and unsaturated fatty acid organic anions.

99. (Amended) The composition of claim 98 wherein said second agent is selected from the group consisting of potassium channel mediating, regulating or blocking agents, calcium channel blocking or regulatory agents, sodium channel blocking agents, steroids, non-steroidal anti-inflammatory agents, aloe vera, chamomile, α-bisabolol, Cola nitida extract, green tea extract, tea tree oil, licorice extract, allantoin, urea, caffeine and other xanthines, and glycyrrhizic acid [and its derivatives].

Please **cancel** claim 100 without prejudice or disclaimer.

101. (Amended) A method for inhibiting skin irritation in an animal subject comprising topically administering to the subject a composition comprising an anti-irritant amount of at least about 50 mM of aqueous-soluble divalent strontium cation and a topical vehicle, wherein said composition is effective to prevent or reduce skin irritation at the skin site where the composition is administered [the composition of claim 62].

Please add the following new claims:

115. (New) The composition of claim 62 wherein said skin irritation is characterized by one or more of sting, burn or itch.

116. (New) The composition of claim 62 wherein said skin irritation is itch.

117. (New) The method of claim 101 wherein said skin irritation is characterized by one or more of sting, burn or itch.

118. (New) The method of claim 101 wherein said skin irritation is itch.

119. (New) The composition of claim 62 further comprising an irritant ingredient, and wherein said composition is effective to prevent or reduce skin irritation attributable to said irritant ingredient.

120. (New) The composition of claim 119 wherein said irritant ingredient is selected from the group consisting of carboxylic acids, keto acids, α-hydroxy acids, β-hydroxy acids, retinoids, peroxides, and organic alcohols, and the irritant ingredient is contained in said composition in an amount of at least 12% by weight.

121. (New) The composition of claim 121 wherein said irritant ingredient comprises an α-hydroxy acid or a salt thereof.

122. (New) The method of claim 101 wherein said skin irritation is attributable to exposure to an irritant ingredient selected from the group consisting of carboxylic acids, keto acids, α-hydroxy acids, β-hydroxy acids, retinoids, peroxides, and organic alcohols.

123. (New) The method of claim 122 wherein said irritant ingredient comprises an α-hydroxy acid or a salt thereof.

124. (New) The method of claim 101 wherein said skin irritation is an irritation inducible by topical application of capsaicin.

125. (New) The composition of claim 68 wherein said skin irritation is attributable to eczema.

126. (New) The method of claim 104 wherein said skin irritation is attributable to eczema.

* * * * * *

The specification has been amended at page 1 to set forth related applications, to which the present application claims the benefit of priority.

The claims have been amended, and certain claims canceled, to expedite examination of the present application, and in view of subject matter already allowed in parent Application Serial No. 08/860,993 (now Patent No. 6,139,850).

Attorney's Docket No.: 14555-011005

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant	: Gary S. Hahn et al.	Art Unit	: Unknown
Serial No.	: 10/189,344	Examiner	: Unknown
Filed	: July 3, 2002		
Title	: FORMULATIONS AND METHODS FOR REDUCING SKIN IRRITATION		

BOX MISSING PARTS
U.S. Patent and Trademark Office
Arlington, VA 22202

SUPPLEMENTAL PRELIMINARY AMENDMENT

Prior to examination, please amend the application as follows:

In the specification:

Replace the paragraph beginning at page 17, paragraph [0035] with the following rewritten paragraph:

-- [0035] In another embodiment, the cation of the present invention may be combined in a formulation with other anti-irritants, such as steroidal or non-steroidal anti-inflammatory agents or other materials such as aloe vera, chamomile, α-bisabolo, cola nitada extract, green tea extract, tea tree oil , licorice extract, allantoin, urea, caffeine or other xanthenes, glycyrrhizic acid and its derivatives, or with other anti-irritant species such as those identified in co-pending U.S. Patent Nos. 5,716,625, 5,756,625, 5,756,107, 5,804,203, 5,958,436, 6,139,850, and 6,455,076, so as to achieve a multiple-anti-irritant effect. --

CERTIFICATE OF MAILING BY FIRST CLASS MAIL

I hereby certify under 37 CFR §1.8(a) that this correspondence is being deposited with the United States Postal Service as first class mail with sufficient postage on the date indicated below and is addressed to the Commissioner for Patents, P.O. Box 2327, Arlington, VA 22202.

September 30, 2003
Date of Deposit

Lucille M. Begalka
Signature

Lucille M. Begalka
Typed or Printed Name of Person Signing Certificate

Replace the paragraph beginning at page 21, paragraph [0042] with the following rewritten paragraph:

[0042] The preferred concentration ranges expressed above contemplate that a typical topical dosage will be approximately 0.5 grams of cation formulation over a 5 cm x 5 cm area of skin (25 cm2). Clinical studies have shown that such preferred concentration ranges are generally effective to inhibit skin irritation and, in typical topical vehicles, are readily formulated and do not leave any significant visible residue when applied to the skin. Higher concentration formulations, such as saturated pastes or other forms, may also be successfully used, particularly where visible appearance is not a limiting consideration (as in therapeutic applications).--

Replace the paragraph beginning at page 22, paragraph [0044] with the following rewritten paragraph:

-- [0044] The optimum concentration of cation of the invention may also be reduced below (or within) the preferred ranges set forth above if some other anti-irritant component is included in the formulation along with the cation component of the invention. In particular, it is contemplated that lower (e.g. halved) amounts of strontium (SR^{2+}) cations may be used, while still maintaining comparable levels of anti-irritant activity, by further including an approximately equal concentration of, for example, a potassium channel mediating, regulating or blocking agent, a calcium channel blocking or regulatory agent, or a sodium channel blocking agent, or other anti-irritant agent such as a steroid or non-steroidal anti-inflammatory agent. Examples of suitable additional anti-irritant ingredients are described in applicants' co-pending U.S. Patent Nos. 5,716,625, 5,756,625, 5,756,107, 5,804,203, 5,958,436, 6,139,850, and 6,455,076, and incorporated by reference in their entirety. --

In the claims:

Amend claims 72-76, 76-80, 83, 86 as follows:

72. (Amended) The composition of claim 62 wherein said skin irritation is attributable to dry skin.

73. (Amended) The composition of claim 62 comprising an amount of strontium cation capable of inhibiting said skin irritation in subjects experiencing the same by an average of at least about 20%.

74. (Amended) The composition of claim 62 comprising an amount of strontium cation capable of inhibiting said skin irritation by at least about 40% in at least 10% of the subjects experiencing the same.

75. (Amended) The composition of claim 62 wherein said composition is formulated as a rectal or vaginal suppository, cream, foam, gel, ointment, douche or enema.

76. (Amended) The composition of claim 62 wherein said composition is formulated for administration to the mouth, throat or lip.

78. (Amended) The composition of claim 62 formulated as a liquid, gel, cream, emulsion, suspension or stick.

79. (Amended) The composition of claim 62 formulated with a physical applicator.

80. (Amended) The composition of claim 62 further comprising, as counteranions to said strontium cation, one or more topically acceptable anion species.

83. (Amended) The composition of claim 62 further comprising at least one second anti-irritant agent.

86. (Amended) A method for inhibiting skin irritation in a human subject comprising topically administering to the subject the composition of claim 62.

121. (Amended) The composition of claim 101 wherein said irritant ingredient comprises an α-hydroxy acid or a salt thereof.--

Please add the following new claims:

127. (New) The composition of claim 62 formulated as a liquid gel, cream, emulsion, suspension or stick.

128. (New) The composition of claim 62 formulated with a physical applicator.

129. (New) The composition of claim 95 wherein said one or more of said counteranions is an organic anion selected from the group consisting of citrate, oxalate, acetate, gluconate, lactate, tartrate, maleate, benzoate, propionate, salicylate, ascorbate, formate, succinate, folinate, aspartate, phthalate, oleate, palmitate, stearate, lauryl sulfate, lanolate, myristate, behenate, caseinate, cyclamate, pantothenate, polyaminopolycarboxylates, saccharin, thioglycolate, laurate, methylparaben, propylparaben, ricinoleate and sorbate organic anions.

130. (New) The composition of claim 62 further comprising at least one second anti-irritant agent.

131. (New) The method of claim 101 wherein said composition is administered within about three hours prior to application to the subject of a second topical formulation containing an irritant ingredient.

132. (New) The method of claim 101 wherein said composition is administered substantially simultaneously with application to the subject of a second topical formulation containing an irritant ingredient.

133. (New) The method of claim 101 wherein said composition is administered to inhibit skin irritation attributable to a pre-existing animal skin disease or skin irritation condition.

134. (New) The method of claim 101wherein said skin irritation is ocular irratation.

135. (New) The method of claim 101 wherein said skin irritation is respiratory system irritation.

136. (New) The method of claim 101 wherein said skin irritation is gastro-intestinal system irritation.

137. (New) The method of claim 101 wherein said skin irritation is reproductive system irritation.

138. (New) The method of claim 101 wherein said skin irritation is irritation of a mucous membrane.

139. (New) The method of claim 101 wherein said skin irritation is irritation of epidermal skin.

140. (New) The method of claim 101 wherein said skin irritation is irritation of dermal skin.

141. (New) The method of claim 133 wherein said skin irritation is attributable to environmental exposure to one or more of sunlight, low humidity, wind, cold temperature, or hot and humid conditions.

142. (New) The method of claim 133 wherein said skin irritation is attributable to exposure to an irritating chemical agent.

143. (New) The method of claim 133 wherein said skin irritation is attributable to one or more of shaving, skin cleansing or bathing, and physical skin trauma.--

In the abstract:

Insert the abstract as follows.

-- ABSTRACT

Compositions and methods are provided for inhibiting skin irritations attributable to chemical irritants or environmental conditions by the application of anti-irritant amounts of aqueous-soluble divalent strontium cation.--

Applicant : Gary S. Hahn et al.
Serial No. : 10/189,344
Filed : July 3, 2002
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REMARKS

Attached is a marked-up version of the changes being made by the current amendment.

Applicant asks that all claims be examined. No fee is believed to be due, however, please apply any other charges or credits to Deposit Account No. 06-1050.

Respectfully submitted,

Date: September 30, 2002

Diane L. Gardner
Reg. No. 36,518

Fish & Richardson P.C.
4350 La Jolla Village Drive, Suite 500
San Diego, California 92122
Telephone: (858) 678-5070
Facsimile: (858) 678-5099

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Version with markings to show changes made

In the specification:

Paragraph beginning at page 17, paragraph [0035] has been amended as follows:

[0035] In another embodiment, the cation of the present invention may be combined in a formulation with other anti-irritants, such as steroidal or non-steroidal anti-inflammatory agents or other materials such as aloe vera, chamomile, α-bisabolo, cola nitada extract, green tea extract, tea tree oil , licorice extract, allantoin, urea, caffeine or other xanthenes, glycyrrhizic acid and its derivatives, or with other anti-irritant species such as those identified in co-pending U.S. Patent [Application Serial] Nos. [__/_____, __/_____, __/_____ and __/_____, __ (attorney docket numbers 210/181, 210/182, 210/183, and 210/184, entitled "Formulations and Methods for Reducing Skin Irritation"), filed on December 21, 1994 by the present inventors] 5,716,625, 5,756,625, 5,756,107, 5,804,203, 5,958,436, 6,139,850, and 6,455,076, so as to achieve a multiple-anti-irritant effect.

Paragraph beginning at page 21, paragraph [0042] has been amended as follows:

[0042] The preferred concentration ranges expressed above contemplate that a typical topical dosage will be approximately 0.5 grams of cation formulation over a 5 cm x 5 cm area of skin (25 cm2). Clinical studies have shown that such preferred concentration ranges are generally effective to inhibit skin irritation and, in typical topical vehicles, are readily formulated and do not leave any significant visible residue when applied to the skin. Higher concentration formulations, such as saturated pastes or other forms, may also be successfully used, particularly where visible [apeparance] appearance is not a limiting consideration (as in therapeutic applications).

Paragraph beginning at page 22, paragraph [0044] has been amended as follows:

[0044] The optimum concentration of cation of the invention may also be reduced below (or within) the preferred ranges set forth above if some other anti-irritant component is included in the formulation along with the cation component of the invention. In particular, it is

contemplated that lower (e.g. halved) amounts of strontium (SR^{2+}) cations may be used, while still maintaining comparable levels of anti-irritant activity, by further including an approximately equal concentration of, for example, a potassium channel mediating, regulating or blocking agent, a calcium channel blocking or regulatory agent, or a sodium channel blocking agent, or other anti-irritant agent such as a steroid or non-steroidal anti-inflammatory agent. Examples of suitable additional anti-irritant ingredients are described in applicants' co-pending U.S. Patent [Application Serial] Nos. [__/_____, __/_____,__/_____ and __/_____,__ (attorney docket numbers 210/181, 210/182, 210/183, and 210/184, entitled "Formulations and Methods for Reducing Skin Irritation"), filed December 21, 1994] 5,716,625, 5,756,625, 5,756,107, 5,804,203, 5,958,436, 6,139,850, and 6,455,076, and incorporated by reference in their entirety.

In the claims:

Claims 54-62 have been added.

Claims 72-76, 78-80, 83, 86 and 121 have been amended as follows:

72. (Amended) The composition of claim [58] 62 wherein said skin irritation is attributable to dry skin.

73. (Amended) The composition of claim [58] 62 comprising an amount of strontium cation capable of inhibiting said skin irritation in subjects experiencing the same by an average of at least about 20%.

74. (Amended) The composition of claim [58] 62 comprising an amount of strontium cation capable of inhibiting said skin irritation by at least about 40% in at least 10% of the subjects experiencing the same.

75. (Amended) The composition of claim [58] 62 wherein said composition is formulated as a rectal or vaginal suppository, cream, foam, gel, ointment, douche or enema.

76. (Amended) The composition of claim [58] 62 wherein said composition is formulated for administration to the mouth, throat or lip.

78. (Amended) The composition of claim [58] 62 formulated as a liquid, gel, cream, emulsion, suspension or stick.

79. (Amended) The composition of claim [58] 62 formulated with a physical applicator.

80. (Amended) The composition of claim [58] 62 further comprising, as counteranions to said strontium cation, one or more topically acceptable anion species.

83. (Amended) The composition of claim [58] 62 further comprising at least one second anti-irritant agent.

86. (Amended) A method for inhibiting skin irritation in a human subject comprising topically administering to the subject the composition of claim [58] 62.

121. (Amended) The composition of claim [121] 101 wherein said irritant ingredient comprises an α-hydroxy acid or a salt thereof.